

Anne Kirchhoff, PhD  
 HIAYA CHAT  
 03/2020



## Consent and Authorization Document

### Huntsman-Intermountain Adolescent Young Adult and Cancer Health Insurance Tools

#### SUMMARY

The purpose of this Huntsman Intermountain Adolescent Young Adult (HIAYA) and Cancer Health Insurance Tools (CHAT) research study is to assess health insurance knowledge, barriers to becoming insured, and concerns about cost of care among adolescents and young adults (AYAs) with cancer.

We are doing this research study because AYAs are more likely to have less comprehensive insurance and have less experience health insurance than older patients. This study will compare two methods of educating participants about health insurance. Whether or not you take part in this study is entirely up to you. You are free to say yes or no. If you agree to participate in this study, you will be randomly (like the flip of a coin) put into to one of two groups.

As a participant in this research study, you will be asked to complete two surveys, possibly participate in 4 videoconference sessions that discuss health insurance, and then be interviewed about how well this program is working. This study team would be in contact with you for about 5 to 6 months. To thank you for your time and effort in this study, we will provide you with two \$20 gift cards, one after each survey. You would also get a gift card for \$20 if you do the interview at the end of the study.

There are some minimal risks for participating in this study include possible breach of confidentiality, or discomfort from answering study questions. There are no expected benefits for participating in this study, but you may learn more about health insurance.

#### STUDY PROCEDURES

There will be around 80 people enrolled in total in this study. If you decide to join this study, you will be randomly assigned to **Group A** or **Group B**. You will be asked to take part in the study for about 5 to 6 months, which will span the study activities of the initial survey, the completion of the program, and a post-program survey. You may also be asked to complete an interview after these activities have been completed with a member of the study team. This research study is projected to end in the summer of 2022.

Both **Group A** participants and **Group B** participants will participate in surveys.

- The surveys will be given at two different times - at study enrollment and again about 2 months after that for a follow-up.
- We will ask you to answer a set of questions about your medical history, basic demographic information, and your insurance experiences, knowledge, and coverage history.
- Answering these questions should take no more than approximately 15 minutes each time. You do not have to answer any questions that make you uncomfortable.

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If you are assigned to **Group A**, the following things will happen:

- Insurance Education Sessions (videoconferencing-based options available): The study team will arrange 4 health insurance experimental educational sessions between you and a patient navigator that will occur every other week over 2 months. The sessions will be approximately 30 to 40 minutes long and can be delivered to you in-person, over the phone, or through an online videoconference portal. If needed, this will allow you to take part in the sessions on a device of your choosing (smartphone, tablet, laptop, desktop computer, etc.) You may opt out of the sessions at any time.
- We will also email you or mail you educational materials on insurance coverage.
- Exit Interview (videoconferencing-based options available): The study will potentially contact you to schedule an interview upon your completion of the health insurance education sessions. This one time interview will be conducted by a study team member, and will be occur in-person, over the phone or through an online videoconference portal. If needed, this will allow you to take part in the sessions on a device of your choosing (smartphone, tablet, laptop, desktop computer, etc.) Interviews are estimated to be about 20 minutes long.

If you are assigned to **Group B**, the following things will happen:

- You will be able utilize the standard patient navigation services as usual.
- We will also email you or mail you educational materials on insurance coverage.
- The study will potentially contact you to schedule an interview about your experiences with navigation. This one time interview will be conducted by a study team member, and will be occur in-person, over the phone or through an online videoconference portal. If needed, this will allow you to take part in the sessions on a device of your choosing (smartphone, tablet, laptop, desktop computer, etc.) Interviews are estimated to be about 20 minutes long.

## PERSON TO CONTACT

Study Team: If you have any questions, complaints, or if you feel you have been harmed by this research please contact Dr. Anne Kirchhoff at the University of Utah by email at [anne.kirchhoff@hci.utah.edu](mailto:anne.kirchhoff@hci.utah.edu) or via phone at 801-587-4084, Monday-Friday 9 a.m. to 4 p.m.

Institutional Review Board: If you have questions regarding your rights as a research subject or if problems arise which you do not feel you can discuss with the study team, please contact Intermountain's IRB at 1-800-321-2107 or [IRB@imail.org](mailto:IRB@imail.org).

## VOLUNTARY PARTICIPATION

Research studies include only people who choose to take part. You can tell us that you don't want to be in this study. You can start the study and then choose to stop the study later without any loss of

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benefits or penalties. This will not affect your relationship with the investigator or anyone on your healthcare team.

All significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the participant through the study staff.

### **COSTS AND COMPENSATION TO PARTICIPANTS**

There are no costs to being in this study. You may be compensated by completing surveys, completing exit interview. In total you will receive between \$40 and \$60 in gift cards for full participation.

### **RISKS**

There are some small risks related to taking part in this study. Questions and discussion about health insurance can be psychologically stressful. As a reminder, you may choose not to answer or discuss any questions that you do not want to and may decide to drop out of the study at any time. There is also a small risk of loss of confidentiality, but we do everything possible to keep your information secure. As with all research, there is also a small possibility for unforeseeable risks. There are no anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

### **WHAT HAPPENS IF I AM INJURED BECAUSE I WAS IN THE STUDY?**

If you become injured while taking part in this study, Intermountain Healthcare can provide medical treatment. We will bill you or your insurance company in the usual way. Because this is a research study, some insurance plans may not pay for your treatment. If you believe you have been injured as a result of being in this study, please call the Principal Investigator right away. You may also contact the Intermountain IRB at 1-800-321-2107 or [IRB@imail.org](mailto:IRB@imail.org).

### **BENEFITS**

There are no direct benefits for taking part in this study. You may learn information about health insurance coverage and access. However, we hope the information we get from this study may help develop a greater insight of AYA cancer patients and insurance understanding in the future. Refusal to participate will involve no penalty or loss of benefits.

### **AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION**

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information like name, current age, gender, insurance information, address, telephone number, and email address.
- Related medical information about you like personal and family medical history, primary diagnosis, age at diagnosis, current and past medications or therapies.

### **HOW WE WILL PROTECT AND SHARE YOUR INFORMATION:**

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We will do everything we can to keep your information private but we cannot guarantee this. Study information (including patient name, medical record number, zip code, email address, telephone number, address, and diagnosis date) will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. If you choose to re-disclose your Personal Health Information (PHI) after the study is complete you will no longer be protected by the Privacy Rule. We may also need to disclose information if required by law.

- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
  - o Members of the research team at University of Utah, Huntsman Cancer Institute, and Intermountain Health Care
  - o The University of Utah and Intermountain Health Care Institutional Review Boards (IRBs), who reviews research involving people to make sure the study protects your rights;
- If we share your information, which is not anticipated at this time, with groups outside of University of Utah Health or Intermountain Healthcare we will not share your name or identifying information. We will label your information with a code number, so they will not know your identity.
- If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at University of Utah Health and Intermountain Healthcare.

#### **WHAT IF I DECIDE TO NOT PARTICIPATE AFTER I SIGN THE CONSENT AND AUTHORIZATION FORM?**

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

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### **CONSENT**

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

**I agree to participate in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.**

\_\_\_\_\_  
Participant's Name

\_\_\_\_\_  
Participant's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Person Obtaining Authorization and Consent

\_\_\_\_\_  
Signature of Person Obtaining Authorization and Consent

\_\_\_\_\_  
Date

**May we contact you for future research studies?**

☐ Yes

Email: \_\_\_\_\_

Phone: \_(\_\_\_\_\_)\_\_\_\_\_

Address: \_\_\_\_\_

☐ No

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